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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,975	01/18/2002	Limin Li	STAN-216	5176

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,975	LI ET AL.	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, as specifically drawn to an antibody that binds specifically to a polypeptide comprising an ubiquitination-regulating domain of a TSG101 protein, classified in class 530, subclass 387.1.

II. Claims 7-12, as specifically drawn to a method of producing an antibody that binds specifically to an ubiquitination-regulating domain of a TSG101 protein, classified in class 424, subclass 130.1.

III. Claims 13 and 17-21, as specifically drawn to a method of treating a condition in a subject comprising administering to a subject a therapeutically effective amount of an agent wherein said agent comprises an ubiquitination-regulating domain, classified in class 424, subclass 184.1.

IV. Claims 14 and 22, as specifically drawn to a method of treating a proliferative disease in a subject comprising administering to said subject a therapeutically effective amount of an agent, said agent modulating the interaction of said TSG101 protein with MDM2, classified in class 514, subclass 1.

V. Claims 15, 17-21, as specifically drawn to a method of treating a proliferative disease in a subject comprising monitoring the level of p53 and treating the subject with an agent, wherein said agent comprises an ubiquitination-regulating domain, classified in class 424, subclasses 9.1, 184.1.

VI Claim 16, as specifically drawn to a method of treating a proliferative disease in a subject comprising monitoring the level of TSG101 and treating the subject with an agent that modulates the interaction of TSG101 with MDM2, classified in class 424, subclass 184.1

VII. Claims 23 and 26-30, as specifically drawn to a cell comprising a polynucleotide encoding an ubiquitination-regulating domain operationally linked to a regulatory sequence that said cell expresses said ubiquitination-regulating domain, classified in class 435, subclass 325.

VIII. Claims 24 and 26-30, as specifically drawn to a cell comprising a polynucleotide encoding an ubiquitination-regulating domain operationally linked to a regulatory sequence and a polynucleotide encoding MDM2 protein operationally linked to a regulatory sequence, such that said cell expresses said ubiquitination-regulating domain, classified in class 435, subclass 325.

IX. Claims 25-30, as specifically drawn to a cell comprising a polynucleotide encoding an ubiquitination-regulating domain operationally linked to a regulatory sequence and a polynucleotide encoding MDM2 protein operationally linked to a regulatory sequence and a polynucleotide encoding p53 protein operationally linked to a regulatory sequence, such that said cell expresses said ubiquitination-regulating domain, classified in class 435, subclass 325.

X. Claims 31-36, as specifically drawn to a method of identifying an agent that modulates the interaction of a TSG101 protein with MDM2, comprising screening candidate agents using a screening assay comprising a cell expressing MDM2 and a polypeptide comprising an ubiquitination regulating domain of TSG101 protein, classified in class 435, subclass 6.

XI. Claim 37, as specifically drawn to a method of modulating a level of MDM2 in a cell, comprising contacting said cell with a polypeptide or derivative thereof that comprises a polypeptide comprising an ubiquitination-regulating domain, classified in class 514, subclass 2.

XII. Claim 38, as specifically drawn to a method of modulating a level of p53 in a cell, comprising contacting said cell with a polypeptide or derivative thereof that comprises a polypeptide comprising an ubiquitination-regulating domain, classified in class 514, subclass 2.

XIII. Claim 39, as specifically drawn to a method of modulating a level of TSG101 in a cell, comprising contacting said cell with an agent that is capable of modulating the interaction of TSG101 protein with MDM2, classified in class 514, subclass 2.

XIV. Claim 40, as specifically drawn to a method of modulating a level of MDM2 in a cell, comprising contacting said cell with an agent that is capable of modulating the interaction of TSG101 protein with MDM2, classified in class 514, subclass 2.

XV. Claim 41, as specifically drawn to a method of modulating a level of p53 in a cell, comprising contacting said cell with an agent that is capable of modulating the interaction of TSG101 protein with MDM2, classified in class 514, subclass 2.

XVI. Claim 42, as specifically drawn to a method of screening for a cellular protein that interacts with an ubiquitination-regulating domain, comprising identifying a cellular protein that binds said ubiquitination-regulating domain, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I and VII-IX represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. For example, Group I is drawn specifically to an antibody that specifically binds to a polypeptide comprising an ubiquitination-regulating domain of a TSG101 protein, whereas Group VII is specifically drawn to a cell comprising a polynucleotide. Furthermore, Group VIII specifically drawn to a cell comprising a polynucleotide encoding an ubiquitination-regulating domain and a polynucleotide encoding MDM2 protein, whereas Group IX drawn to a cell comprising a polynucleotide encoding an ubiquitination-regulating domain and a polynucleotide encoding MDM2 protein and a polynucleotide encoding p53 protein.

The invention of Groups II-VI and X-XVI are materially distinct methods of which differ at least in objectives, method steps, reagents and/or dosage and/or schedules used, response variables, and criteria for success. For example, Group II is drawn to a method of producing an antibody that binds specifically to an ubiquitination-regulating domain of a TSG101 protein, whereas Group IV is drawn to a method of treating a proliferative disorder. Furthermore, Group XI specifically drawn to a method of modulating a level of MDM2 in a cell, comprising contacting said cell with a polypeptide, whereas Group XIV is specifically drawn to a method of modulating a level of MDM2 in a cell, comprising contacting said cell with any and all agents.

The inventions of Group II and the method of Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibody of group I can be made by another and materially different process such as using hybridomas or by using various host animals.

The inventions of Groups VII-IX and the method of Group VIII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of using a cell in a screening assay can be practiced with another materially different product such as any one of the cells represented by Groups VII-IX.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to

maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

GARY NICKOL
PRIMARY EXAMINER